

# EXHIBIT 9

**From:** Mark Morken  
**To:** Scott Waite  
**CC:** Michelle Stevens; Mark Scott; Inmaculada Soria  
**Sent:** 7/10/2015 10:32:52 PM  
**Subject:** RE: [EXTERNAL] RE: Message to address safety and efficacy of forced air warming

Hi Scott,

Michelle and I did meet yesterday and my action was to follow up which I am doing now. It is not entirely clear to us what Dr. Stefan is asking for, was there an initial email that started this conversation or was it your email to him? What are his findings and own data? Also we would need to really understand what type of study is being proposed. Given the ongoing legal situation, decisions were made previously (at a high level) not to pursue clinical research work on this topic.

Michelle has limited availability next week to meet as she is traveling. Can you propose some possible dates/ times?

Thanks,

Mark



**Mark A. Morken** | Clinical Research Manager  
3M Infection Prevention Division  
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**From:** Scott Waite

**Sent:** Friday, July 10, 2015 2:51 PM

**To:** Mark Morken

**Cc:** Scott Waite; Michelle Stevens; Mark Scott

**Subject:** Re: [EXTERNAL] RE: Message to address safety and efficacy of forced air warming

Good afternoon Mark,

It's been a week, and I would like to set up a meeting to discuss a study, having Mark Scott on the call. Please advise how to pursue. Considering the pending Stryker threat situation, this would be extremely valuable.

Thank you

Scott

Scott R. Waite BSN RN CCRN  
Perioperative Technical Consultant  
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On Jul 7, 2015, at 2:48 PM, Mark Morken <[mamorken@mmm.com](mailto:mamorken@mmm.com)> wrote:

Hi Scott,

Thanks for your email. Given the ongoing legal situation, Michelle Stevens and I will discuss the comments from Dr. Stefan and then provide a response.

Mark

**Mark A. Morken** | Clinical Research Manager  
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**From:** Scott Waite  
**Sent:** Monday, July 06, 2015 10:44 AM  
**To:** Mark Morken  
**Subject:** Fwd: [EXTERNAL] RE: Message to address safety and efficacy of forced air warming

Scott R. Waite BSN RN CCRN  
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Begin forwarded message:

**From:** Scott Waite <[srwaite@mmm.com](mailto:srwaite@mmm.com)>  
**Date:** July 6, 2015 at 11:31:15 AM EDT  
**To:** Mark Scott <[njscott2@mmm.com](mailto:njscott2@mmm.com)>, Sally Bull <[sjbull@mmm.com](mailto:sjbull@mmm.com)>  
**Subject:** Fwd: [EXTERNAL] RE: Message to address safety and efficacy of forced air warming

Good afternoon,

would someone be able to reach out to Dr. Stefan regarding the study I would be happy to arrange a meeting.  
Thank you Scott

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Begin forwarded message:

**From:** "Ianchulev, Stefan" <[sianchulev@tuftsmedicalcenter.org](mailto:sianchulev@tuftsmedicalcenter.org)>  
**Date:** July 2, 2015 at 2:58:20 PM EDT  
**To:** Scott Waite <[srwaite@mmm.com](mailto:srwaite@mmm.com)>  
**Subject:** [EXTERNAL] RE: Message to address safety and efficacy of forced air warming

Thank you very much, Scott, for addressing the issues we have. However, my observations are not based on other studies and influenced by your competitors. I have plenty of own data to support my findings. I am Familiar with Dan Sessler's and Andrea Kurz's retrospective evaluation of the temperature behavior in a single institution over the initial 2 hrs of surgery. I completely agree with them and the conclusion that a warming of the patient should be continuous and start as early as possible. There are however no data to address the SSI and the swab results from the surgical site based on pre-prepping of

the surgical site when the forced air device is working. Thus it cannot be recommended to start the device earlier than the draping of the site.

The second point on the prewarming in the holding area - we tried this and it was very cumbersome in our institution and actually hindering some of the processes so we had to discontinue it. It also added more cost.

Certainly, we can work together on addressing those issues and finding a way to improve on your device. Would be happy to even conduct a study addressing some of the concerns above in a unbiased fashion.

Kind regards,  
Stefan

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**From:** Scott Waite [ [srwaite@mmm.com](mailto:srwaite@mmm.com) ]

**Sent:** Thursday, July 02, 2015 2:27 PM

**To:** Ianchulev, Stefan

**Subject:** Message to address safety and efficacy of forced air warming

Good Afternoon Dr. Stefan Ianchulev,

My name is Scott Waite, I am the perioperative technical consultant for 3M's Infection Prevention Division. We have heard recent news of a "Recommended Practice of not turning on the Bair Hugger to warm patients till after the patient is draped.. This email will speak to addressing the safety and efficacy of forced air warming, and the importance of prewarming the patients.

I wanted to provide you with recent evidenced based practice that supports the safety of forced air warming. Please feel free to email and forward to any member of your staff who may have questions. If you have any further questions, I would be happy to address them, or Mark Scott, our Global Product Manager for Patient Warming.

Research shows that effective prewarming banks heat in the core and periphery 30 minutes prior to anesthesia induction, and prevents redistribution temperature drop in the patient after that first hour of anesthesia induction. Sessler concludes, "Temperatures drop 1.6 degrees after anesthesia induction after the first hour." Patients need continuous patient warming throughout the perioperative area. "Mild Perioperative Hypothermia which is common during major surgery, may promote surgical-wound infection by triggering thermoregulatory vasoconstriction, which decreases subcutaneous oxygen tension. reduced levels of oxygen in tissue impair oxidative killing by neutrophils and decrease the strength of the healing wound by reducing the deposition of collagen. Hypothermia also directly impairs immune function. (Kurz, Sessler, p.1209)

Thank you for addressing the safety and efficiency of forced air warming. On behalf of 3M's Infection Prevention Department Laboratory and Technical Services, we wanted to thank you for reaching out to us. We are aware that one of our competitors, Augustine Temperature Management, and its associated web site, [www.StopSurgicalInfection.org](http://www.StopSurgicalInfection.org), has been e-mailing care providers across the country citing several recent journal

publications (most directly supported by Augustine Temperature Management, with several co-authored by a former employee of the company). To address this misinformation, we would like to direct you to resources we feel will help care providers quickly gain access to the facts about forced air warming and our history of safe, effective warming products. These resources include a link to our dedicated informational site ( [www.FAWfacts.com](http://www.FAWfacts.com) ) along with some citations and independent review of the safety of forced air warming published in the last couple of years and detailed below:

1- ECRI Publication (April 2013):

Following the publication of an ECRI investigation into possible links between forced air warming and OR air contamination, many customers received emails from Augustine Temperature Management. The emails misrepresented the article's conclusion, which in fact stated there was, "insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods."

ECRI responded to the Augustine communications by adding the following Editor's Note" to the article's cover page:

The ECRI article is an unbiased review of this issue and is a valuable tool for addressing concerns. When providing the link to customers (we cannot supply the actual article electronically, only the link) make sure it takes them to the article with the Editor's note.

Here is that link:

[https://www.ecri.org/Documents/Reprints/Forced-Air\\_Warming\\_and\\_Surgical\\_Site\\_Infections\\_\(Health\\_Devices\).pdf](https://www.ecri.org/Documents/Reprints/Forced-Air_Warming_and_Surgical_Site_Infections_(Health_Devices).pdf)

*(See attached file: Forced-Air\_Warming\_and\_Surgical\_Site\_Infections(Health\_Devices).pdf)*

## 2- Parvizi-Karam citation

I am attaching below Parvizi-Karam citation and the facts they shared about FAW:

*(See attached file: Parvizi-Karam-Study.pdf)*

## 3- International Conference Consensus (November 2013):

The outcome of the International Consensus Meeting on Periprosthetic Joint Infection, Delegates from various disciplines including orthopedic surgery, infectious disease, musculoskeletal pathology, microbiology, anesthesiology and many others evaluated the available evidence on a number of topics to reach consensus regarding current practices for management of SSI/PJI.

One of the questions investigated was whether forced air warming increases the incidence of SSI. With agreement from 89 percent of delegates, the consensus states, "...no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice."

We have the following section, that relates to forced-air warming, from the ICC.

*(See attached file: ICC consensus.docx)*

4- FAW Course in AORN / Augustine Op-Ed / Author (Paul Austin et al.) response:

In October 2013 issue of AORN journal, included the following CE course which had same conclusion as the ECRI research:

In March 2014 issue of AORN Journal contained an Op-Ed from Scott Augustine - "Another perspective on forced-air warming and the risk of surgical site infection".

This Op-Ed prompted a response from the author, Paul Austin et al., both attached below:

*(See attached file: AORN March 2014 Op-Ed Augustine.pdf)(See attached file: AORN March 2014 Op-Ed Author Response.pdf)(See attached file: Austin et al.pdf)*

5- Legal Lawsuit:

3M is aware of this lawsuit, and as is the case with any allegation of patient injury, 3M takes this very seriously. At this time we cannot comment on this lawsuit's allegations, but we will fully investigate the specific circumstances of this claim.

3M is confident that the science supports the safety and efficacy of the 3M Bair Hugger forced-air warming system, and supported by a number of clinical studies and scientific research. We look forward to the opportunity to prove in court what has already been confirmed by years of experience and millions of uses—that forced air warming is a safe, effective warming technology.

It is important to note that the allegations the plaintiff made in its initial court have not been tested, supported by factual or expert evidence, or ruled on by the court at this time.

Our primary concern is the safety of the patient and the personnel that use our products. If you have any additional concern, I would like to take the opportunity to offer that a team of our scientific and technical experts, to present the scientific and clinical evidence of our products. I would also like to be with the team, to assure you that we stand behind any product we offer to our valuable customers and partners. That's what we stand for as a company, and we have proven that over 110 years serving our community and our global customers.

A new article was recently published that addresses a "Hot Dog" product

To support this conversation I have included the Brauer Efficacy of FAW study which shows that blanket design makes a distinct difference in patient warming efficacy. Here, Brauer reports that we have the lowest nozzle temperature, but the greatest heat transfer.

(See attached file: *Brauer Efficacy of forced-air warming systems with full body blanket.pdf*)

In other words, we use the highest, safest nozzle temperatures and efficiently (and evenly) move the warm air through the blankets channels and manifolds and then to the skin surface where heat transfer occurs through a evenly spaced pattern of air-hole perforations. Without the air hole perforations, air-warmed blankets are effectively a air-warmed conductive offering.

Please call me with questions..

Kind Regards

Scott

## REFERENCE

Kurz, Andrea, M.D., Sessler, Daniel I M.D., and Lenhardt, Rainer M.D. Perioperative Normothermia To Reduce The Incidence Of Surgical-Wound Infection And Shorten Hospitalization. The New England Journal OF Medicine 1996; 334: 1209-1215

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